

## MULTIWAY VALVE

DESCRIPTIONBackground of the Invention.

5 The present invention relates to a flow shut-off element.

In particular, the flow shut-off element according to the present invention is intended for applications in the medical field and, in greater detail, this device can be used in circuits for peritoneal dialysis.

10 As is known, a circuit for peritoneal dialysis consists of at least one tube connected to the patient's peritoneal cavity; in practice, the tube consists of a surgically implanted fixed catheter having an outlet inside the peritoneal cavity, and a portion outside the  
15 body to which is connected a further length of tubing designed to be replaced periodically.

The circuit thus has a first infusion line connected to one or more bags containing fresh fluid for introduction into the patient's peritoneal cavity and a  
20 second drainage line for the waste fluid, designed to carry the fluid located in the patient's peritoneal cavity to one or more bags for subsequent disposal.

In particular, the infusion and drain lines are joined by a Y-connector to a third line in communication with  
25 the fixed catheter and consequently with the peritoneal cavity.

Briefly, in a peritoneal dialysis operation the dialysis fluid which has remained for the necessary time in the patient's peritoneal cavity has to be  
30 drained off and sent to the collection bags for disposal, and the Y-connector then has to be flushed through by passing fresh fluid from the infusion line

- 2 of 21 -

to the drain line, after which, in a final stage of infusion, a fresh fluid has to be introduced into the patient's peritoneal cavity.

Consequently, in order to carry out the aforesaid operations, it is necessary to use shut-off elements capable of operating in the area of the junction between the various tubes to ensure the correct flow of the fluids.

A first known technique requires the use of clamps (at least one for each tube), which are operated manually, thus mechanically deforming the tubing to the point at which its cross section is completely closed.

In particular, for carrying out the aforesaid operations, the infusion line is first closed to allow the fluid to pass from the patient towards the disposable bags; secondly the tubing leading towards the peritoneal cavity is closed, enabling the connection area to be washed by passing fresh fluid towards the disposable fluid bag, after which the drain line is closed, thus allowing fresh fluid to be introduced into the peritoneal cavity.

Clearly, since manual opening and closing operations have to be performed on the tubing, a degree of experience and attention is required from the user who might otherwise make mistakes in the sequence of stages, or even carry out incorrect operations which could result in serious harm to the patient's health.

A further known technique according to Patent no. EP 768099 requires the use of a stopcock consisting of a valve body on which three channels for the passage of fluids converge.

- 3 of 21 -

The valve body has a central cavity which communicates with the aforesaid channels, and which is designed to receive a projecting portion of a movable selector.

5 The rotation of the selector creates different paths for the fluid within the stopcock, these paths being created simply by the angular position of the said selector.

10 This stopcock is also provided with suitable projections located within the cavity formed by the valve body, and with corresponding notches formed on a cylindrical portion of the said selector.

15 In practice, the function of these elements is to signal to the user that the correct angular positions of the selector have been reached, these positions providing an optimal predetermined passage of fluid within the stopcock.

However, the known technique summarized above has certain drawbacks and/or operational limitations.

20 In the first place, the valves of the known type described above have no versatility at all, and are difficult to adapt.

If these devices were to be modified and/or adapted in any way, it would be necessary to replace most parts, if not all, of the stopcock.

25 Furthermore, with the aforementioned shut-off element it is not possible to specify the sequence of successive operations which the valve is to perform; in particular, the operator only has the sensation of correct positioning in the various operating  
30 conditions, but there is no indication as to the correctness of the valve opening/closing sequence being executed by the device.

- 4 of 21 -

### Summary of the Invention.

The object of the present invention is therefore essentially to overcome the aforesaid drawbacks.

5 A first object of the invention is to provide a flow shut-off element which is as versatile and adaptable as possible.

10 A further object of the invention is to maintain maximum reliability of the device without essentially detracting from the intrinsic simplicity of construction of the known devices, and while also keeping the costs low, in view of the fact that the valves to which the invention relates are generally of the disposable type.

15 A subsidiary object of the invention is to provide a shut-off element in which the correct sequence of operations is made compulsory, in such a way that a user cannot inadvertently carry out these operations in an incorrect temporal sequence.

20 Finally, a further object is to prevent the re-use of these valves when they have already been used.

These and other objects which will be made clear in the course of the description are essentially achieved by a flow shut-off element according to the present claims.

### Brief Description of the Drawings.

25 Further characteristics and advantages will be made clear by the following detailed description of a preferred, but not exclusive, embodiment of a flow shut-off element according to the illustrations in the attached drawings, in which:

30 - Figure 1 shows a perspective view of a valve body according to the present invention;

- 5 of 21 -

- Figure 2 shows a view from above of the body of Figure 1;
- Figure 3 shows a transverse section through the valve body shown in Figure 1;
- 5 - Figure 4 shows a longitudinal section through the valve body shown in Figure 1;
- Figure 5 shows an auxiliary element which can be associated with the valve body shown in Figure 1;
- 10 - Figure 6 shows a detail of the positioning means of the auxiliary element of Figure 5;
- Figure 7 shows a lateral view in partial section of the auxiliary element of Figure 5;
- Figure 8 shows in a perspective view from above a selector which can be associated with the valve  
15 body shown in Figure 1;
- Figure 9 shows in a perspective view from below the selector shown in Figure 8;
- Figure 10 shows in a lateral view the selector shown in Figure 8;
- 20 - Figure 11 shows a section taken through the line A-A of the selector of Figure 10;
- Figure 12 shows a transverse section taken through the line B-B of the selector of Figure 10;
- Figure 13 shows in a schematic way a variant of  
25 the auxiliary element of Figure 5; and
- Figure 14 shows in a schematic way a circuit for peritoneal dialysis.

Detailed Description.

- 6 of 21 -

With reference to the aforesaid figures, the number 1 indicates the whole of a flow shut-off element for use, in particular, in medical applications, and more particularly in circuits for peritoneal dialysis.

5 As shown in Figure 14, the shut-off element 1 is designed to operate (as explained more fully below) in the area of the junction of the infusion line 100 and the drain line 200 with the inlet line 300 leading to the patient's peritoneal cavity.

10 To provide greater structural detail, it can be seen that the shut-off element consists of a valve body 2 (see Figures 1 to 4) which has an essentially discoid profile and has a plurality of accesses 4, 5 and 6, of which there are three in this particular case, designed  
15 to be connected, respectively, to the infusion line 100, to the drain line 200, and to the patient line 300.

In particular, the terminal portions of the tubes forming the aforementioned lines are engaged with the  
20 projecting portions of these accesses and the connection is secured by the friction generated between the material forming the tubes and the material, for example polycarbonate, from which the valve body is made.

25 The accesses 4, 5 and 6 thus form three channels which can put the infusion line 100, drain line 200 and patient line 300 directly into fluid communication with an inner cavity 3 of the valve body 2.

The flow shut-off element 1 also comprises a selector 7  
30 (see Figures 8 to 12) also of essentially discoid shape, which can be associated with the valve body 2 and is movable relatively to the latter into a predetermined number of operating positions in which it forms, by interacting with the said valve body,

- 7 of 21 -

predetermined paths in which the flow of the fluid is permitted and/or shut off between the said accesses 4, 5 and 6.

5 In particular, the selector, made for example from polyethylene by injection moulding, is provided with a projecting portion 13 which has an essentially cylindrical profile and is at least partially shaped in a complementary way to the inner cavity 3 of the valve body 2.

10 It should be noted that the portion 13 can alternatively have a conical shape (obviously with a small degree of taper), in order to improve the fluidtightness between the said portion 13 and the cavity 3.

15 In particular, in operating conditions, the selector 7 is mounted on the valve body 2 in such a way that the projecting portion 13 is inserted into the cavity 3 in a fluidtight way.

20 The projecting portion 13 has a cross section (shown in Figure 11) in which can be seen channels 16 designed to interact with the accesses 4, 5 and 6 formed in the valve body 2 in order to create various paths for the fluid within the shut-off element, according to the relative angular positions of the selector 7 and the  
25 valve body 2.

In detail, the first, second and third accesses 3, 4 and 5 are brought into fluid communication in a predetermined sequence by relative rotations of the selector about the axis of rotation 15.

30 According to the peritoneal dialysis procedure, the selector 7 must be capable of switching the shut-off element at least between a condition in which the flow of fluid is prevented; a condition in which fluid

- 8 of 21 -

passes from the third to the second access 6, 5, in which the fluid is allowed to drain from the patient's peritoneal cavity 301 to the waste bags 201; a condition in which fluid passes from the first to the second access 4, 5, in which the connector is washed by making fresh fluid pass towards the waste bag 201; and a condition in which fluid passes from the first to the third access 4, 6, in which fresh fluid can be infused from the bags 101 into the patient's peritoneal cavity 301. The configuration of the channels 16 and the arrangement of the accesses 4, 5 and 6 is such that a rotation of the selector from an initial position in the direction of the arrow 23 shown in Figure 8 makes it possible to pass in succession from the fluid flow shut-off condition to the drain condition, to the washing condition and then to the infusion condition, finally reaching a condition in which the passage of fluid is stopped within the shut-off element.

Advantageously, the shut-off element according to the present invention also comprises an auxiliary element 8 shown in Figures 5, 6, 7 and 13, which also has an essentially discoid shape and is designed to be removably associated with the valve body 2.

In this context it should be noted that the valve body 2 is provided with one or preferably numerous locating blocks 25, which, more precisely, consist of small catches projecting from the channels 4, 5 and 6 (see Figure 1); these locating blocks enable the auxiliary element 8 to be positioned correctly on the said valve body.

As can be seen in Figure 7, the auxiliary element 8 has corresponding notches 26 designed to receive the said locating blocks 25 of the valve body 2.



- 9 of 21 -

During assembly, the auxiliary element 8 is positioned to bear on the valve body 2 and then the projecting portion 13 of the selector is inserted into the cavity 3 of the valve body where it is engaged by a snap fit.

- 5 It should also be noted that the valve body has an inner perimetric wall 21 delimiting the inner cavity 3.

In a corresponding way, the auxiliary element 8 has a central through cavity 24, through which an upper portion 21a of the perimetric wall 21 passes during  
10 assembly.

The selector 7 is also provided with a circular ring 7a which is coaxial with the projecting portion 13 and interacts with this portion to delimit a cavity 14 for engagement with the valve body 2.

- 15 In other words, the upper portion 21a of the perimetric wall 21 is designed to be inserted and guided in its movement by the engagement cavity 14 of the said selector into a condition in which the various components are engaged.

- 20 Turning now to the illustration in Figure 5, it can be seen that the auxiliary element 8 is provided with positioning means 9 for determining when one of the predetermined operating positions of the selector is reached.

- 25 In particular, the selector 7 can comprise a predetermined number of catches and/or notches 10 (a plurality of notches being provided in the illustrated embodiment), while the positioning means 9 can have at least one corresponding catch or notch 11 (in the  
30 present case, a single locking catch is provided) designed to engage in at least one of the said catches and/or notches 10.

- 10 of 21 -

The positioning means 9 consist, in particular, of an elastic element 12 which extends along a curved axis from the main body of the auxiliary element 8 and has the locking catch 11 at its free end. This catch 11  
5 interacts, in particular, with the notches 10 of the selector 7, which are formed on the aforesaid circular ring 7a. In particular, following a rotation of the selector 7, the configuration of the notches 10 and the catch 11 is such that the elastic element 12 is  
10 deformed in a radial direction until the catch 11 snaps into an angularly successive notch 10.

The particular configuration of the catch 11 and the notches 10 is such that the selector 7 can rotate with respect to the valve body 2 only in the direction  
15 indicated by the number 23 in Figure 8.

Rotation in the opposite direction is prevented by the undercut of the catch 11 which bears on the corresponding undercuts formed in the circular ring of the selector (see, in particular, Figure 9).

20 It can be seen in Figure 6 that the positioning means 9 also comprise a stop projection 22 which can form a mechanical stop to the rotary movement of the selector 7.

In particular, the function of the stop projection 22  
25 is to delimit the end of travel of the selector 7.

In other words, when the valve body 2, the auxiliary element 8 and the selector 7 have been assembled together in the correct initial position, it is possible to make successive rotations of the selector  
30 in the direction indicated by the arrow 23 of Figure 8 into the various operating conditions of the shut-off element.

- 11 of 21 -

The reaching of the various stages of operation is indicated by the snap-fitting of the catch 11 into the corresponding notches 10, and, when all the operating positions have been passed through in sequence, the  
5 stop projection 22 interacts with the said notches 10 and thus prevents further rotation in the direction of the arrow indicated by the reference 23.

At the same time, the catch 11 inserted into another corresponding notch 10 prevents movement in the reverse  
10 direction, thus effectively preventing the re-use of the shut-off element.

Finally, it should be noted that the selector 7 has at least one aperture 17 for permitting views of corresponding areas of the underlying auxiliary  
15 element.

Thus different positions of the selector 7 relative to the valve body 2 enable different portions of the upper surface 8a of the auxiliary element 8 to be viewed.

This upper surface 8a has, in particular, predetermined  
20 visual representations 18 illustrated by way of example in Figures 5 and 13.

The representations 18 can be, in particular, graphic symbols and/or alphanumeric indications and/or colours relating to the paths in which the fluid flow is  
25 permitted and/or shut off between the said accesses.

With reference to the screen-printed auxiliary element shown in Figure 5, it can be seen that, in the initial assembly position, the aperture 17 is located over the wording "START"; a first rotation in the direction of  
30 the arrow 23 places the aperture over the wording "DRAIN" and at the same time the shut-off element moves from a condition in which no flow of fluid is permitted within the cavity 3 to a condition in which the fluid

- 12 of 21 -

is allowed to drain from the patient's peritoneal cavity 310 to the waste bags 201.

A further rotation of the selector 7 places the aperture 17 over the wording "FLUSH", where the shut-off element is in the flushing condition, allowing fresh fluid to flow towards the waste bags 201.

A further rotation places the aperture 17 over the wording "FILL" and the configuration of the shut-off element is such that fresh fluid is allowed to flow towards the patient's peritoneal cavity 301.

A further rotation in the clockwise direction then places the aperture over the wording "END" in which no flow of fluid is permitted within the shut-off element.

In this final condition, it is no longer possible to carry out any rotation in either the clockwise or the anti-clockwise direction, and the said shut-off element therefore has to be removed.

Finally, as shown in Figure 8, the selector 7 has a grip portion 19 to enable the operator to rotate it with respect to the valve body 2; the grip portion 19 is, in particular, formed by suitable stiffening ribs 20 which extend transversely with respect to the axis of rotation 15.

The invention yields considerable advantages.

In the first place, the presence of an auxiliary body, which carries the screen-printed wording relating to the operations which the shut-off element is executing and also carries the positioning means which provide an active indication of the reaching of the correct position, imparts a greater versatility to the device.

This is because the shut-off element can be adapted simply by replacing the auxiliary disc in such a way

- 13 of 21 -

that the wording and/or graphic representations appearing on it can be modified.

Additionally, a modification of the positioning means of this auxiliary element makes it possible to carry  
5 out larger or smaller relative rotations and to stop the shut-off element in different angular positions.

These advantages are achieved without essentially affecting the simplicity of construction and the production costs of the shut-off element, which has to  
10 be replaced after every use.

Furthermore, the particular configuration of the positioning means and of the corresponding notches present on the selector make it possible to specify a single direction of rotation and therefore a sequence  
15 of the possible operations to be executed, with no possibility of any error by the operator.